IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMICUS THERAPEUTICS US, LLC and AMICUS THERAPEUTICS, INC., *Plaintiffs*, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS, INC., *et al.* *Defendants*.	C.A. No. 1:22-cv-01461-CJB ANDA Case (Consolidated) **PUBLIC VERSION – CONFIDENTIAL MATERIAL OMITTED**

DEFENDANTS AUROBINDO PHARMA LTD. AND AUROBINDO PHARMA USA, INC.'S BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF ALL ASSERTED PATENTS UNDER 35 U.S.C. § 101

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Defendants, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., (collectively for identification purposes, "Aurobindo"), through their undersigned counsel, hereby submit their Brief in Support of Aurobindo's Motion for Summary Judgment of Invalidity of the Asserted Patents, in accordance with Rule 56 of the Federal Rules of Civil Procedure. In support of their Motion, Aurobindo states as follows:

I. INTRODUCTION

As the case presently stands, Plaintiffs have asserted four patents against Aurobindo's Abbreviated New Drug Application ("ANDA") No. 217786 seeking approval from the U.S. Food & Drug Administration ("FDA") for Aurobindo's migalastat hydrochloride capsules, EQ Base 123 mg (*i.e.*, 150 mg) strength, which is related to Plaintiffs' migalastat product sold under the brand name Galafold in the U.S. and Europe, perhaps among other places: U.S. Patent Nos. 11,663,388 ("'388 patent"); 11,833,164 ("'164 patent"); 12,042,489 ("'489 patent"); and 12,042,490 ("'490 patent") (collectively, the '388, '164, '489 and '490 patents are referred to herein as the "Asserted Patents").[1] Aurobindo contends the Asserted Patents are invalid as obvious in accordance with 35 U.S.C. § 103 and, separately, as being directed to unpatentable subject matter under 35 U.S.C. § 101 (permitting patents for "any new and useful ***process, machine, manufacture, or composition of matter***, or any new and useful improvement thereof" (emphasis added)).

Aurobindo here seeks to prevent Plaintiffs from improperly extending their patent protection for the very same methods of treatment Plaintiffs already claimed in unrelated patents that preceded the Asserted Patents by eight years or more. Since at least as early as April 12, 2012, Plaintiffs have sought patent protection for a method of treating Fabry disease patients "in need

[1] Exhibit citations refer to the exhibits submitted with the Declaration of George J. Barry III in Support of Aurobindo's Motion for Summary Judgment ("Barry Decl."), submitted simultaneously herewith. The '388, '164, '489 and '490 patents are Exhibits 1-4, respectively, to the Barry Declaration.

thereof" with migalastat (also referred to as "1-deoxygalactonojirimycin" or "DGJ") in either freebase or salt forms every other day at a dosage equivalent to 123 mg of the freebase and 150 mg of migalastat hydrochloride. *See* Ex. 5 (U.S. Patent No. 9,000,011 ("011 patent")), at 7:39-53, claim 1,; Ex. 6 (Benjamin Tr.) at 97:14-23; Ex. 8 (Castelli Tr.) at 148:8-16.) The '011 patent issued April 7, 2015. *See* Ex. 5. The '388 patent, the earliest issued of the Asserted Patents, issued April 25, 2023. *See* Ex. 1.

The only material difference between the earlier-issued '011 patent claims and the recently issued Asserted Claims is that the Asserted Claims further describe the Fabry patient(s) in need of migalastat, namely, and redundantly, those whose genetic mutations are determined to be migalastat amenable. *Compare*, *e.g.*, Ex. 1 at claim 1 and Ex. 2 at claim 23 *with* Ex. 5 at claim 1. As explained in the specifications of the Asserted Patents, the genetic mutations identified in the Asserted Claims were determined to be amenable to treatment with migalastat using chemical assays that are not claimed in the asserted claims and that nobody will ever need to replicate to practice the claimed inventions. *See* Ex. 6 at 49:23-50:7; Ex. 8 at 93:5-94:10; *see also* Exs. 1-4. Thus, Plaintiffs aim to stretch their patent protection for their Galafold product by improperly incorporating limitations directed to a Fabry mutation's amenability (or correlation) to migalastat, which is a naturally occurring phenomenon. But for those improper limitations, the scope of the Asserted Claims is identical to the scope of the '011 patent claims. *Compare* Exs. 1-4 (asserted claims) *with* Ex. 5 (claims).

Whether the Asserted Claims are invalid under § 101 turns on a simple application of binding, on-point precedent to the plain language of the claims themselves. The asserted claims each seek to re-claim treatment methods through the addition of limitations directed to a diagnostic finding of an inherent characteristic: a Fabry patient's amenability to migalastat based on the

characteristics of the Fabry patient's disease-causing mutation. That is clearly impermissible under 35 U.S.C. § 101, which precludes patent claims directed to natural phenomena, as discussed *infra*. Therefore, Aurobindo respectfully requests entry of summary judgment of invalidity of all patent claims asserted in this case on the grounds that the Asserted Claims are directed to unpatentable subject matter under 35 U.S.C. § 101.

II. STATEMENT OF NATURE AND STAGE OF THE PROCEEDINGS

This case concerns Hatch-Waxman Act patent litigation initiated by Plaintiffs in response to Aurobindo's filing of its ANDA.[2] Plaintiffs accuse Aurobindo of infringing claims 8 and 36 of the '388 patent; claims 23-27 of the '164 patent; claims 17 and 23 of the '489 patent and claim 9 of the '490 patent (collectively, "Asserted Claims").

Based on the plain language of the Asserted Claims, to narrow issues for trial, Aurobindo stipulated to infringing the Asserted Patents to the extent they are not determined to be invalid (*see* D.I. 191), thus leaving only the question of their validity, which Aurobindo challenges as improperly claiming unpatentable matter, in violation of § 101, and, in any case, as obvious pursuant to 35 U.S.C. § 103. Fact discovery has concluded. Expert reports have been exchanged, and the expert discovery period has expired, though the parties have since worked cooperatively to conduct expert depositions, which are ongoing but will be concluded this month. A five-day bench trial is scheduled to begin September 29, 2025 at 9 a.m.

III. SUMMARY OF THE ARGUMENT

Each of the Asserted Claims is directed to a method of treating Fabry disease patients with migalastat or a salt thereof. Some of the Asserted Claims describe the administration of migalastat without specifying the form of the compound or the dosage to be administered. *See*, *e.g.*, Ex. 1 at

[2] When Galafold was approved, it was granted regulatory New Chemical Entity (NCE) exclusivity, which precludes FDA from approving Aurobindo's ANDA through February 10, 2026.

claim 1. Others claim the administration of migalastat hydrochloride in the amount of 150 mg. *See*, *e.g.*, Ex. 1 at claim 36. And others claim the administration of migalastat in an amount equivalent to 123 mg of free base, which equates to 150 mg of migalastat hydrochloride. *See* Ex. 2 at claim 23; Ex. 6 at 74:15-24. In this way, the Asserted Claims are no different than the claims in Plaintiffs' earlier filed/issued '011 patent, which claims administration, to Fabry patients in need thereof, of 150 mg 1-deoxygalactonojirimycin, which the '011 patent discloses is the same thing as 150 mg of migalastat hydrochloride. *See* Ex. 5 at 7:37-53; *see also* Ex. 6 at 74:15-24.

The Asserted Claims add to the '011 patent claims only by further describing Fabry patients actually in need of migalastat by reference to specific Fabry disease-causing genetic mutations determined to be amenable to migalastat treatment. This is the only distinction of significance between the Asserted Claims and Plaintiffs' earlier '011 patent claims. *Compare* Exs. 1-4 (asserted claims) Claims *with* Ex. 5 (claims). A genetic mutation's amenability to migalastat therapy is a natural phenomenon determined through the use of one or more chemical assays described more or less in Exhibits 1-5. Therefore, identifying those mutations in a patent claim does not confer patentable characteristics to the claimed inventions. In accordance with 35 U.S.C. § 101, the results of Amicus' diagnostic studies on Fabry mutations are not patentable. *See*, *e.g.*, *Mayo Collaborative Svcs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 87 (2012) (discussed *infra*).

Therefore, Aurobindo respectfully requests entry of summary judgment of invalidity for all Asserted Claims.

IV. CONCISE STATEMENT OF MATERIAL FACTS

A. Plaintiffs' Earlier Patent Protection

The '011 patent issued April 7, 2015, with 11 claims. *See* Ex. 5. Claim 1 is exemplary and claims, "A method for treatment of Fabry disease in a patient in need thereof comprising administering to the patient a therapeutically effective dose of 150 mg 1-deoxygalactonojirimycin

or a salt thereof every other day." The claims of the '011 patent do not identify specific genetic mutations that cause Fabry disease. *See* Ex. 5 at claims 1-11.

The inventors on the '011 patent are David Lockhart, a former Amicus employee and one of the authors of one of the prior art references Aurobindo has cited against the Asserted Patent as grounds for invalidation for obviousness, and Jeff Castelli, one of the inventors on three of the four Asserted Patents. *See* Ex. 5; Ex. 8 at 129:4-23; *see also* Exs. 1-4. Plaintiffs have listed the '011 patent along with the Asserted Patents and 58 similar patents in FDA's *Orange Book: Approved Products with Therapeutic Equivalence Evaluations* ("Orange Book"). *See* Ex. 8, *available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=208623&Appl_type=N* (last visited June 12, 2025).

B. Patents-in-Suit and Asserted Claims

a. '388 Patent

The application leading to the '388 patent was filed October 23, 2020. *See* Ex. 1. It identifies Jeff Castelli and Elfrida Benjamin as inventors and Amicus as the assignee and claims priority to several earlier applications that led to the issuance of U.S. Patent Nos. 10,857,141; 10,874,655; 10,471,053 and 10,251,873. The '388 patent further claims priority to two provisional patent applications, one of which was filed May 30, 2017, and February 6, 2018. Although Aurobindo does not concede the point, Aurobindo does not challenge Plaintiffs' assertion that the proper priority date for the claims asserted from the '388 patent is May 30, 2017. Plaintiffs have asserted claims 8 and 36 from the '388 patent, which depend directly or indirectly from claim 1, which claims:

> A method of treating Fabry disease, the method comprising administering migalastat to a patient in need thereof, wherein the patient has an α-galactosidase A protein comprising a HEK assay amenable mutation selected from the group consisting of: A13P, A20D, Q57L, G80D, P146S, D175E, K213R, K213M, I242F,

> M267T, A309V, V316I, V316G, P323R, A352G, R356P, T385A, V390M, and G395A.

See Ex. 1. The '388 patent is related to the '489 and '490 patents by common parent patent applications and shares a common specification with the '489 and '490 patents. *See* Exs. 1, 3-4. The '388 patent is not related to the '011 patent. *See* Exs. 1, 5.[3]

b. '164 Patent

The application leading to the '164 patent was filed August 7, 2020. *See* Ex. 2. It identifies Elfrida Benjamin and Xiaoyang Wu as inventors and Amicus as the assignee and claims priority to a provisional patent application filed August 7, 2019. Although Aurobindo does not concede the point, Aurobindo does not challenge Plaintiffs' assertion that the proper priority date for the claims asserted from '164 patent is August 7, 2019. Plaintiffs have asserted claims 23-27 from the '164 patent, with claim 23 being the independent claim from which claims 24-27 depend. Claim 23 of the '164 patent claims:

> A method of treating Fabry disease in a human patient in need thereof, the method comprising orally administering migalastat to the patient about 123 mg free base equivalent of migalastat or a salt thereof every other day, wherein the patient has an α-galactosidase A mutation selected from the group consisting of: Y184S, N228H or T412I.

See Ex. 2. The '164 patent is not related to any other Asserted Patent or the '011 patent. *See* Exs. 1-5.

[3] The parties have agreed that the term "HEK assay amenable mutation" as used in the Asserted Claims from the '388, '489 and '490 patents, should be construed to mean a "mutant form of α-galactosidase A ("α-Gal A") showing a relative increase of ≥ 1.2-fold over baseline and an absolute increase of ≥ 3.0% wild-type α-Gal A activity in the presence of 10 μmol/l migalastat determined using the Good Laboratory Practice ("GLP")-validated HEK assay."

c. '489 Patent

The application leading to the '489 patent was filed May 31, 2023. *See* Ex. 3. It identifies Jeff Castelli and Elfrida Benjamin as inventors and Amicus as the assignee and claims priority to several earlier applications that led to the issuance of U.S. Patent Nos. 11,813,255; 11,666,564; 11,304,940; 11,612,593; 10,857,141; 10,874,655; 10,471,053 and 10,251,873. The '489 patent further claims priority to two provisional patent applications, one of which was filed May 30, 2017, and February 6, 2018. Although Aurobindo does not concede the point, Aurobindo does not challenge Plaintiffs' assertion that the proper priority date for the claims asserted from the '489 patent is May 30, 2017. Plaintiffs have asserted claims 17 and 23 from the '489 patent, which depend directly or indirectly from claim 11, which claims:

> A method of treating Fabry disease, the method comprising administering migalastat to a patient in need thereof, wherein the patient has an α-galactosidase A protein comprising a HEK assay amenable mutation selected from the group consisting of: A13T, N34T, M42K, L54F, P60T, E87D, L89F, Y123C, H125L, I133M, K140T, F145S, P146R, Y152H, D165G, p.M187_S188dup, V199G, M208R, I219L, N224T, Q250R, G261C, G271D, M284V, I303F, D322N, G325R, K326N, G334E, E358Q, E358D, G361E, G375E, T412N and M421V.

See Ex. 3. The '489 patent is related to the '388 and '490 patents by common parent patent applications and shares a common specification with the '388 and '490 patents. *See* Exs. 1, 3-4. The '489 patent is not related to the '011 patent. *See* Exs. 3, 5.

d. '490 Patent

The application leading to the '490 patent was filed May 31, 2023. *See* Ex. 4. It identifies Jeff Castelli and Elfrida Benjamin as inventors and Amicus as the assignee and claims priority to several earlier applications that led to the issuance of U.S. Patent Nos. 11,813,255; 11,666,564; 11,304,940; 11,612,593; 10,857,141; 10,874,655; 10,471,053 and 10,251,873. The '490 patent further claims priority to two provisional patent applications, one of which was filed May 30, 2017,

and February 6, 2018. Although Aurobindo does not concede the point, Aurobindo does not challenge Plaintiffs' assertion that the proper priority date for the claims asserted from the '490 patent is May 30, 2017. Plaintiffs have asserted claim 9 from the '490 patent, which depends indirectly from claim 1, which claims:

> A method of treating Fabry disease, the method comprising administering migalastat to a patient in need thereof, wherein the patient has an α-galactosidase A protein comprising a HEK assay amenable mutation selected from the group consisting of: I242F, G334E, N34D and p. V254del.

See Ex. 4. The '490 patent is related to the '388 and '489 patents by common parent patent applications and shares a common specification with the '388 and '489 patents. *See* Exs. 1, 3-4. The '490 patent is not related to the '011 patent. *See* Exs. 3, 5.

C. Additional Relevant Facts

1. Inventor Elfrida Benjamin, Ph.D., was deposed in this case in her personal and representative capacities on February 6, 2025. *See* Exs. 6, 7.

2. Inventor Jeffrey P. Castelli, Ph.D., was deposed in this case in his personal and representative capacities on February 21, 2025. *See* Exs. 8, 9.

3. Only Fabry patients with a migalastat amenable mutation are likely to receive a therapeutic benefit from migalastat, though therapeutic benefit from migalastat is not guaranteed even for patients with an amenable mutation. *See* Ex. 6 at, *e.g.*, 52:21-54:22; 78:24-79:9, 84:22-85:1; and 135:19-136:11; Ex. 8 at, *e.g.*, 38:24-41:6.

4. A Fabry patient's responsiveness to migalastat is not dependent upon the patient's Fabry disease-causing mutation as having been subjected to an assay to determine migalastat amenability or otherwise identified as migalastat amenable. *See* Ex. 6 at 50:20-51:4; Ex. 8 at 89:16-90:1; 95:4-96:8; 167:6-19; 177:25-178:12

5. 123 mg of migalastat freebase is equivalent to 150 mg migalastat hydrochloride. *See* Ex. 6 at 74:15-24.

6. Mutations that cause Fabry disease are naturally occurring. *See* Ex. 6 at 81:18-25; Ex. 8 at 84:3-17.

7. The only information conveyed by the migalastat amenability assays is whether the mutation tested will be amenable to treatment with migalastat. *See*, *e.g.*, Ex. 6 at 31:6 to 32:1; Ex. 8 at 91:5-9.

8. Once a mutation has been identified as amenable using the so-called GLP-HEK Assay, it is not necessary to re-test the same mutation for amenability. *See* Ex. 6 at 49:23-50:7; Ex. 8 at 93:5-94:10.

Aurobindo respectfully submits that the facts set forth *supra* in this section IV are undisputed.

V. ARGUMENT

A. Summary Judgment Standards

> Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585 n.10, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986). If the moving party has sufficiently demonstrated the absence of such a dispute, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Id.* at 587 (internal quotation marks, citation and emphasis omitted). If the nonmoving party fails to make a sufficient showing in this regard, then the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). During this process, the Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150, 120 S. Ct. 2097, 147 L. Ed. 2d 105 (2000).

> However, in order to defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co.*, 475 U.S. at 586. The "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986) (emphasis in original). Facts that could alter the outcome are "material," and a factual dispute is "genuine," only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. "If the evidence is merely colorable . . . or is not significantly probative . . . summary judgment may be granted." *Id.* at 249-50 (internal citations omitted). A party asserting that a fact cannot be—or, alternatively, asserting that a fact is—genuinely disputed must support the assertion either by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials;" or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B).

Baxter Healthcare Corp. v. Nevakar Injectables, Inc., Civil Action No. 21-1184-CJB, 2025 U.S. Dist. LEXIS 46836, at *5-6 (D. Del. Mar. 14, 2025) (Burke, MJ). Patents are presumed to be valid, and Aurobindo has the burden of proving invalidity by clear and convincing evidence. *See*, *e.g.*, *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1291 (Fed. Cir. 2013) (reciting the well-known standard)

B. Summary Judgment is Warranted Under § 101

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. "While the scope of section 101 is broad, "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *See S.I.SV.E.L. Societa Italiana per lo Sviluppo Dell' Elettronica S.p.A v. Rhapsody Int'l, Inc.*, C.A.

Nos. 18-69-MN-CJB, 18-70-MN-CJB, 2019 U.S. Dist. LEXIS 37508, at *7 (D. Del. Mar. 8, 2019) (citing *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 134 S. Ct. 2347, 2354, 82 L. Ed. 2d 296, 189 L. Ed. 2d 296 (2014)).

In *Alice Corp.*, the U.S. Supreme Court set out a two-step framework for assessing whether a patent contains eligible subject matter under Section 101.

> First, [the Court] must determine whether the claims at issue are directed to one of those patent ineligible concepts. If so, [the Court] then ask[s], what else is there in the claims before us? To answer that question, [the Court] consider[s] the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application. We have described step two of this analysis as a search for an inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.

See Alice Corp. Pty. Ltd., 573 U.S. at 217-18.

Alice concerned claims directed to an abstract concept that were ultimately held to be unpatentable. *Id.* at 227. A couple years before *Alice*, though, the Supreme Court addressed a patent directed to natural phenomenon that is on point with the instant case and, Aurobindo respectfully submits, counsels for entry of summary judgment of invalidity in this case. *See Mayo Collaborative Svcs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 87 (2012).

At issue in *Mayo* were

> patent claims covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high. The claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side effects.

Id. at 72.

Unlike in *Mayo*, the Plaintiffs in this case do not claim any sort of improvement to any product or process. They do not claim a method for assessing migalastat amenability, for example, and the claims do not describe a process for doing so. They simply reclaim a previously patented method for treating Fabry disease and add adjectives to further describe the patient in need. Thus, *Mayo* presented a much closer question than the fact of this case. Consequently, the *Mayo* decision's determination that the method of optimization claims then before the Court were unpatentable applies equally to the Asserted Claims. As the *Mayo* Court reasoned:

> [The patents at issue] set forth laws of nature—namely, relationships between concentrations of certain metabolize in the blood and the likelihood that a dosage of thiopurine drug will prove ineffective or cause harm. Claim 1, for example, states that *if* the levels of 6-TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8x108 red blood cells, *then* the administered dose is likely to produce toxic side effects. While it takes human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

Mayo, 566 U.S. at 77.

Similarly here, by identifying the specific mutations in the Asserted Claims, Plaintiffs have merely informed patent readers about a laboratory assay-based correlation that can be drawn between a Fabry patient's disease-causing mutation and migalastat. They have added no inventive concept to the Asserted Claims. Therefore, Aurobindo respectfully submits, the Asserted Claims are invalid under *Mayo*. *See also Ass'n for Molecular Pathology v. Myriad Gentics, Inc.*, 569 U.S. 576, 591-92, 596 (2013) (*Myriad*) (holding that Myriad's discovery of "a gene associated with increased risk of breast cancer" and their identification of mutations of that gene that increase the risk" were not patent eligible under 35 U.S.C. § 101); *Athena Diagnostics, Inc. v. Mayo*

Collaborative Services, LLC, 915 F.3d 743, 754-55 (Fed. Cir. 2019) (holding that claims directed to the correlation between the presences of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases patent ineligible); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1377 (Fed. Cir. 2016) (holding that claims directed to the relationship between non-coding and coding sequences in linkage disequilibrium and the tendence of such non-coding DNA sequences to be representative of the linked coding sequences are patent ineligible as directed to a natural phenomenon); *Endo Pharm. Inc. v. Actavis Inc.*, No. 14-1381-RGA, 2015 WL 7253674, at *2-*3 (D. Del. Nov. 17, 2015) (holding that the human body's reaction to a drug is "unquestionably a natural law" and dose titration in response is a mere application of the law of nature and not inventive)

Moreover, the facts of this case are clearly distinguishable from decisions finding claims arguably directed to unpatentable subject matter as including that inventive step. *See Myriad*, 569 U.S. at 594-95 (distinguishing patent ineligible claims from claims directed to cDNA, which is human generated); *Endo Pharms. Inc. v. Teva Pharms. USA, Inc.*, 919 F.3d 1347, 1353 (Fed. Cir. 2019) (holding claims directed to a multi-step process for treating pain in a renally impaired patient patent eligible); *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd.*¸887 F.3d 1117, 1133-36 (Fed. Cir. 2018) (distinguishing *Mayo* and holding method of treatment claims patent eligible where they were, unlike the Asserted Claims in this case, directed to a novel method of treating a discease" that recited "more than the natural relationship between CYP2D6 metabolizer genotype and the risk of QTc prolongation").

In *Mayo*, the U.S. Supreme Court sounded alarms the relevant facts of the underlying action should trigger as well:

> Our conclusion rests upon an examination of the particular claims before us in light of the Court's precedents. Those cases warn us

> against interpreting patent statutes in ways that make patent eligibility depend simply on the draftsman's art without reference to the principles underlying the prohibition against patents for natural laws. They warn us against upholding patents that claim processes that too broadly pre-empt the use of natural law. And they insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an inventive concept, sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.

Mayo, 566 U.S. at 72 (quotations, citations and correction marks omitted).

The crafty draftsmanship on display among Plaintiffs' patents, both asserted and nonasserted, is precisely the type of patent games the holding in *Mayo* intended to prevent. *Mayo* and its progeny warrant summary judgment in this case. Therefore, Aurobindo respectfully requests entry of summary judgment in its favor on Plaintiffs' claims for infringement and Aurobindo's defense of invalidity under 35 U.S.C. § 101.

VI. CONCLUSION

Aurobindo respectfully submits that the Asserted Claims reflect crafty draftsmanship designed to sow confusion with the aim of extending Plaintiffs' monopoly on the market for migalastat in treating Fabry patients. Despite Amicus's posturing in this case regarding the significance of migalastat and the amenability assay or assays to the Fabry disease community, the Asserted Claims do not claim those assays or describe any process or improvement to their previously claimed method of treating Fabry disease with 150 mg of migalastat. The Asserted Claims do not more than draw a correlation between certain genetic mutations and migalastat and, therefore, are directed to natural phenomenon without adding inventive step. They are, therefore, invalid under 35 U.S.C. § 101, and, thus, Aurobindo respectfully requests that entry of summary judgment be entered in its favor on Plaintiffs' claims for infringement and Aurobindo's defense of

invalidity. Aurobindo respectfully submits it has met its burden of proving invalidity of the Asserted Claims by clear and convincing evidence.

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Respectfully submitted,

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